mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Updates to Immunosuppressive Guidance

MLN Matters Number: MM11072
Related Change Request (CR) Number: CR 11072
Related CR Release Date: December 31, 2018
Effective Date: April 3, 2019
Related CR Transmittal Number: R4189CP
Implementation Date: April 3, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for immunosuppressive drugs provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11072 updates guidance in the Medicare Claims Processing Manual regarding the provision of covered immunosuppressive drugs to inpatients for use after a transplant procedure. Make sure your billing staffs are aware of these updates.

BACKGROUND

Inpatient facilities (for example, hospitals) are responsible for providing drugs during a beneficiary's inpatient stay. However, once the beneficiary has returned home, Part B suppliers (including pharmacies) provide the immunosuppressive drugs, and the DME MACs make the payments for Part B covered immunosuppressive drugs.

In certain cases, a beneficiary who has received a transplant does not return home immediately after discharge. In order to ensure timely beneficiary access to prescribed immunosuppressive medications at the time of discharge, suppliers may deliver the initial prescriptions of a beneficiary's immunosuppressive drugs to an alternate address, such as the transplant facility or alternative location where the beneficiary is temporarily staying, for example, temporary housing, instead of delivering the drugs to the patient's home address.

Note that this is an optional, not mandatory, process. If the supplier ships immunosuppressive drugs to an alternate address, all parties involved, including the beneficiary and the transplant facility, must agree to the use of this approach. All other applicable Medicare and DME MAC billing requirements continue to apply. This provision is limited to prescriptions that will be billed on the first claim that the supplier submits for the beneficiary after the beneficiary is discharged from an inpatient facility.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

The following conditions also apply:

- The immunosuppressive drug must be medically necessary on the date of discharge; that is, there is a valid prescription for an immunosuppressive drug that is reasonable and necessary and is clinically required to be available no later than the date of discharge for home use.
- Early and/or direct delivery to the transplant facility does not change the inpatient facility's responsibility to provide all immunosuppressive drugs that the beneficiary requires during their entire inpatient stay.
- The supplier must not:
  - Mail, or otherwise dispense the drugs any earlier than 2 days before the beneficiary's anticipated discharge date. (It is the supplier's responsibility to confirm the beneficiary's discharge date.)
  - Submit a claim for payment prior to the beneficiary's actual date of discharge.
  - Claim payment for additional costs that the supplier incurs in ensuring that the immunosuppressive medications are delivered to the alternative location. Additionally, the supplier also must not bill Medicare or the beneficiary for redelivery if it is necessary.

This new guidance may be used with the early delivery provision already described in Section 80.3.3, and all other applicable Medicare and DME MAC billing requirements continue to apply.

ADDITIONAL INFORMATION

The official instruction, CR11072, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4189CP.pdf. The revised manual section is attached to the transmittal.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
December 31, 2018	Initial article released.